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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,378	10/25/2000	John Jianhua Chen	S63.2-9503	2980

490 7590 11/21/2002

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 11/21/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,378

Applicant(s)

CHEN ET AL.

Examiner

Sow-Fun Hon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

Withdrawn Rejections

1. The 35 U.S.C. 112, 2nd paragraph rejections in Paper # 11 (mailed 07/03/02) of claims 1-26, 31-36 have been withdrawn due to Applicant's amendment in Paper # 12 (filed 09/05/02).
2. The 35 U.S.C. 103(a) rejections in Paper # 11 (mailed 07/03/02) of claims 1-26, 31-36 have been withdrawn due to Applicant's amendment in Paper # 12 (filed 09/05/02).
3. The obviousness double patenting rejections in Paper # 11 (mailed 07/03/02) of claims 11, 15-18 have been withdrawn due to Applicant's terminal disclaimer in Paper # 13 (filed 09/05/02).

New Rejections

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1-8, 12-26, 31, 33, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al. (US 4,448,195) in view of Zdhrala.

LeVeen et al. has a balloon catheter wherein the balloon and catheter are a one piece unit with the balloon being a thin catheter wall portion of exact shape and size, and that it can be formed by expanding a distal tube portion of the catheter. LeVeen et al. teaches that the catheter may be formed by blowmolding tubing with fine fibers (column 1, lines 5-50), but fails to teach that the the fibers are polymeric or the orientation of the fibers.

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Zdrahala teaches extruded catheter tubing with improved longitudinal stiffness (abstract). The orientation of the liquid crystal polymer at the distal tube end is substantially longitudinal, to provide a catheter section of relatively low rotational stiffness and relatively high longitudinal stiffness which is desired for a distal catheter tip to facilitate advancement through small arteries or veins (column 2, lines 42-52). A suitable liquid crystal polymer is a terpolymer of hydroxybenzoic acid, ethylene glycol and terephthalic acid (column 3, lines 55-60). It is generally preferred for the composition to contain from 5 to 35 weight percent of the liquid crystal polymer as a mixture. The matrix may be composed of polyurethanes and thermoplastic elastomers (column 5, lines 15-50) which are either compliant or semi-compliant and are taught to be elastomers such as polyester-polyether block copolymers (HYTREL) and polyamide-polyester (PEBAX) block copolymers (column 4, lines 15-30) which have melting points between 150 °C and 230 °C.

Zdrahala teaches that the tube may be extruded with no relative rotation between orifice and mandrel, but with stretching imposed by orienting apparatus, with the result that the fibrils of such tubing are generally parallel to the tubing axis where such a structure tends to have relatively high longitudinal stiffness (column 8, lines 1-5) which means that the longitudinal elongation of the catheter section would be minimal, and precludes longitudinal expansion of 5 % beyond the original preinflation state. Other additives such as compatibilizers (surfactants) are taught (column 5, lines 16-30). Orientation of the liquid crystal fibrils in a helical direction is also taught (column 5, lines 50-55).

Zdrhala teaches that an added layer may be placed over or within (or both) the liquid crystal mixture (column 6, lines 5-25), thus teaching a multilayer catheter tubing. Zdrhala teaches that the catheter tubings are for balloon angioplasty (PCTA) (column 1, lines 10-25).

Because Zdrhala teaches that the catheters are for balloon angioplasty, and that the composition provides the catheters with improved longitudinal stiffness for facilitating advancement through small arteries and veins, it would have been obvious to one of ordinary skill in the art to have used the catheter tubing of Zdrhala for the one-piece balloon catheter in the invention of LeVeen et al. in order to obtain a balloon catheter with the desired longitudinal stiffness for facilitating advancement through small arteries and veins.

6. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al. in view of Zdrhala as applied to claims 1-8, 12-26, 31, 33, 36 above, and further in view of Cozewith et al.

Leveen et al. has been discussed above, and teaches a catheter balloon with reinforcing fibers, but fails to teach the compatibilizer.

Zdrhala has been discussed above, and teaches a catheter tubing wherein the liquid crystal polymer ingredient may be desirably semi-compatible with the particular structural plastic matrix (column 5, lines 35-40) and that the blended composition may include block copolymers such as copolyester elastomers, polyolefins and copolymers of ethylene with acrylates (column 4, lines 15-30) and the specific use of compatibilizers (surfactants) (column 5, lines 20-35). Zdrhala, however, fails to teach that any block copolymer in the blend is specifically a compatibilizer.

Cozewith et al. discloses that it is well known in the art to use block copolymers as compatibilizers for emulsifying polymer/polymer blends (column 1, lines 15-25) and that the

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block copolymer compatibilizer is composed of two or more polymer molecules of different chemical composition which are covalently bonded in an end-to-end fashion (column 1, lines 15-35).

Because Cozewith et al. discloses that it is well known in the art to use block copolymers as compatibilizers for emulsifying polymer/polymer blends, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a block copolymer taught by Zdrhala as the compatibilizer in the catheter tubing of Zdrhala, in order to use the catheter tubing of Zdrhala as the catheter balloon tubing in the invention of LeVeen et al., such that a balloon catheter with the desired compatibility between matrix and fiber and thus the desired constrained inflation and longitudinal stiffness is obtained.

7. Claims 32, 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al. in view of Zdrhala as applied to claims 1-8, 12-26, 31, 33, 36 above, and further in view of Jorgensen.

Leveen et al. has been discussed above, and teaches a catheter balloon with reinforcing fibers, but fails to teach the dimensions of the fibers.

Jorgensen has a dilation balloon for securing to (the distal end of) a catheter, wherein the balloon is formed of an elastomeric skin with a constraining structure embedded in the elastomeric skin. The constraining structure is formed of liquid crystal polymer fibers with a diameter (thickness) of less than 15 microns. Jorgensen teaches that the fibers allow unrestrained expansion of the balloon from deflation to inflation diameter size, but provide enough reinforcement to effectively restrain the balloon from undergoing any radial expansion beyond the inflation diameter size (column 3, lines 25-50). One of ordinary skill in the art would

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have chosen fibers with a specific elongation to break of 50-500 % for a specific constrained inflation of the catheter balloon.

Because Jorgensen teaches that the fibers allow unrestrained expansion of the balloon from deflation to inflation diameter size, but provide enough reinforcement to effectively restrain the balloon from undergoing any radial expansion beyond the inflation diameter size, and LeVeen et al. teaches that the fibers are fine fibers, it would have been obvious to one of ordinary skill in the art to have used the fiber diameters taught by Jorgensen for the fine fibers in the invention of LeVeen et al. in order to obtain a fiber reinforced catheter balloon with the desired unrestrained deflation to inflation balloon diameter, and effective reinforcement to restrain radial expansion beyond the desired inflation diameter.

Response to Arguments

8. Applicant's arguments with respect to claims 1-26,31-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

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11/15/02


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

11/18/02